Animal and Plant Health Inspection Service

Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis

Proposed Rule: Movement of Certain Genetically Engineered Organisms (7 CFR 340)

Docket Number: 08-023-1

September 2008

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Executive Summary

Under various statutes, regulatory oversight of biotechnology is shared by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA). The proposed rule among other things would clarify USDA APHIS' role in the regulatory process. Currently, APHIS monitors field-testing, movement, and importation of GE products under the Plant Protection Act (PPA, 7 USC 7701-7772) and regulations found in 7 CFR 340. Under the PPA, the USDA has the authority to regulate the movement, importation, or release of plant pests or potential plant pests. Since the regulations in 7 CFR 340 were first promulgated in 1987, and with the advancements in technology and the experience gained in over 20 years of oversight, it has become necessary to update the regulations. In addition, the 2008 Farm Bill (The Food, Conservation, and Energy Act of 2008) enacted most recently contains provisions that need to be incorporated into the proposed rule. The proposed changes are intended to improve the clarity and transparency of the regulations and provide clearer understanding of APHIS's role in the regulatory process.

Benefits of the proposed regulations would be improved efficiency, improved public confidence in the regulatory system, and improved clarity and transparency of the regulations. Many provisions of the proposed rule would improve the efficiency of the biotech regulatory process. Various exemptions are proposed along with a streamlined permit system, performance-based shipping standards, and a provision to provide for additional exemptions without amending the regulations. Overall, these regulatory amendments are likely to benefit consumers, producers, public and private research, and the Agency.

The proposed rule's greater clarity and transparency in comparison to the existing regulations is expected to enhance the general public's perception of APHIS' regulation of the importation, interstate movement, and release into the environment of GE organisms. In

particular, public-sector biotech research that is generally conducted on a much smaller scale than that of large agri-business enterprises can be expected to benefit from the proposed procedural changes to part 340.

There are several potential costs associated with the proposed rule. USDA APHIS would incur costs associated with outreach activities, developing guidance documents, training, and upgrading the current permit system. In addition, because of the new definition of the scope of the regulations, APHIS may devote more resources to consultations if regulated parties request consultation in order to determine whether particular GE organisms are or are not subject to the regulations. Such consultation should decrease after the first year or two of implementation, as such determinations of regulated status accumulate and become the basis for guidance of general applicability.

Regulated entities would incur costs associated with rule familiarization, recordkeeping and reporting, and providing information during the application process. However, these costs may be offset by costs savings due to various exemptions and performance-based shipping standards provided in the proposed regulations. Currently, there are no estimates of the Agency's costs of outreach activities, development of guidance documents, and employee training related to the proposed rule. It is estimated that changes to the current permit system during the transition period may cost APHIS approximately $500,000. However, the current permit system can be adapted to accommodate applications during the transition period.

Potentially affected entities fall under various categories of the North American Industry Classification System and while economic data was not available on business size for most entities, based on the industry estimates obtained from the Economic Census and the Census of Agriculture we can assume the majority of the businesses that may be affected by the proposed rule would be small. In terms of economic impacts, we anticipate that the proposed rule would

only impose minimal costs on the regulated entities through rule familiarization, the provision of required information during the application process, and recordkeeping and reporting. However, the level of increased costs associated with record keeping and reporting costs are not clear because much of the required information, although not formerly an explicit requirement of the regulations, is the type of information that GE organism developers keep for business and research purposes. The cost of rule familiarization is also not expected to be significant; the regulated community would already be familiar with the current regulations. In addition, affected entities may also incur costs related to changes necessitated by the new permitting system. APHIS welcomes public comment on the proposed rule's possible impacts.

Introduction

This Regulatory Impact Analysis (RIA) and Regulatory Flexibility Analysis examine the costs and benefits of the proposed amendments to 7 CFR 340, "Introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests." The regulations in 7 CFR 340 are administered by the Biotechnology Regulatory Services of the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS). As an introduction to the analysis, background information on the recent growth of biotechnology and the current regulatory environment are presented. Potential impacts of the proposed rule are then described.

Background

The adoption of genetically engineered (GE) crops by farmers worldwide has become increasingly widespread. In 2005, 8.5 million farmers in 21 countries planted 222 million acres of GE crops. The United States, Argentina, Brazil, Canada, and China are the major GE crop adopters. In 2007, 91 percent of soybean, 73 percent of corn, and 87 percent of cotton acreages planted in the United States were genetically engineered (NASS 2008). In addition to the major field crops, some fruits and vegetables in the United States are GE varieties.

The benefits associated with the use of some GE crops already in production include higher yields, lower pesticide costs, and overall savings in management time. There are also environmental benefits from reduced pesticide use. Attempts have been made to quantify the benefits that have occurred as a result of the adoption of GE crops and, according to a recent survey, farm-level net economic benefits worldwide from the adoption of GE crops were estimated to be $7 billion in 2006 (Brookes and Barfoot 2008). Total net benefits, 1996-2006, were estimated to be $34 billion. Of this total estimated net welfare gains, the United States

experienced the largest benefit, with $15.8 billion; followed by Argentina, $6.6 billion; China, $5.8 billion; and Brazil, $1.9 billion (Brookes and Barfoot 2008). U.S. farmers' welfare gains from the adoption of biotechnology ranged from 29 to 42 percent of total net welfare gains (Price *et al*. 2005; Falck-Zepeda, Traxler, and Nelson 2000).

The high rate of GE crop adoption by farmers has been driven by an increase in consumption of product developed with the use of GE techniques. However, studies that quantify consumers' benefits from the use of biotechnology are limited, as most studies tend to focus on the direct adopters of biotechnology, i.e., the producers. Price *et al.* (2006) found consumers do benefit from the adoption of *Bt* cotton.

Overall, consumers' gains from the adoption of various GE crops have been estimated to range from 4 to 17 percent of total net welfare gains (Price *et al.* 2005; Falck-Zepeda, Traxler, and Nelson 2000).

Crop producers and consumers are not the only beneficiaries of recent advances in biotechnology. The providers of biotechnology have also benefited from the increased adoption and consumer demand for GE products. Intellectual property right laws have offered incentives for the private sector to invest in research and development of GE products, and as a result, plant breeding expenditures have largely shifted from the public to the private sector (Fuglie and Heisey 2007). As private research spending has increased, so has the number of firms engaged in this type of research. However, consolidation and mergers during the 1990's resulted in an industry dominated by large companies. Currently, 80 percent of biotech traits that have been approved are owned or co-owned by four firms (Bayer Crop Science, DuPont, Monsanto, and Syngenta) or their subsidiaries (Kalaitzandonakes, Alston, and Bradford 2007).

With regard to the beneficial effects for the environment of GE plants in commercial production, their production has resulted since 1996 in decreases in the global use of pesticides

by 286 million kg (Brookes and Barfoot 2008). These declines represent 7.9 percent reductions. In terms of greenhouse gases, one study estimated cultivation using no-tillage systems associated with GE crops modified for herbicide tolerance to reduce fuel use by 32.52 liters/ha (89 percent)[1] compared to conventional methods, and 14.7 liters/ha (76 percent) compared to reduced tillage methods. These fuel-use reductions translate into reductions of carbon dioxide emissions of 89.44 kg/ha and 40.43 kg/ha, respectively. An American Soybean Association survey[2] showed significant reductions in tillage, and therefore in fuel use, by growers of glyphosate-tolerant soybeans. The fuel reductions were estimated as 1.26 gallons per acre, or, for the 56 million acres of glyphosate-tolerant soybeans planted in 2001, 70 million gallons of fuel saved and associated greenhouse gas emissions avoided. Overall in 2006, the total global carbon dioxide savings associated with the use of GE crops were 1.2 billion kg. This is equivalent to removing 540,000 cars from the streets for a year.

The Current Regulatory Environment

Under the 1986 Coordinated Framework for the Regulation of Biotechnology, the regulation of GE products is shared by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA).

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) FDA regulates the safety of all food (other than meat, poultry and egg products), including food and feed developed from biotechnology. Under FFDCA § 301 (Prohibited Acts), the adulteration of food and the introduction of adulterated food into interstate commerce are prohibited. Under FFDCA § 402,

[1] Calculations of percentage reductions in fuel use were based on an on-farm survey for various row crops in Nebraska. This survey was conducted by Paul J. Jasa, University of Nebraska

[2] Cited in Fawcett, Richard and Towery, Dan. Conservation Tillage and Plant Biotechnology: How New Technologies Can Improve the Environment By Reducing the Need to Plow. Conservation Technology Information Center, West Lafayette, Indiana.

foods are considered to be adulterated, for example, if they contain any poisonous or deleterious substance which may render the food injurious to health, or if they contain an unapproved food additive. FDA has authority to remove food that has been found to be unsafe from the market.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides the EPA with regulatory authority over pesticides. Certain features of the FIFRA are applicable when considering the regulation of pesticidal substances produces by certain GE plants. Pesticides are defined as substances intended for preventing, destroying, repelling, or mitigating any pest such as an insect, rodent, fungus, or weed. FIFRA generally prohibits the distribution and sale of pesticides in the United States unless the pesticide is registered for a particular use or exempt from regulation. The registration process requires the submission of substantial data and supporting evidence that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." Pesticide registration is not required when EPA issues an experimental use permit. A permit is issued only if the applicant needs the field tests to accumulate the data necessary to register the pesticide. General authority to promulgate regulations for the enforcement of FIFRA is assigned to the Administrator of EPA.

USDA APHIS regulates field-testing, movement, and importation of GE organisms under the Plant Protection Act (PPA, 7 U.S.C. 7701-7772) and regulations found in 7 CFR 340. Under the PPA, the USDA has the authority to regulate the movement, importation, or release of plant pests or potential plant pests. The Secretary of Agriculture has authority to restrict importation and interstate movement of plants, plant products, biological control organisms, noxious weeds, or other articles when necessary, to prevent the dissemination of plant pests or noxious weeds. This includes genetically engineered plants that may pose damage to crops, public health, or the environment. Under the current regulation, APHIS determines whether to authorize the field-testing of agricultural biotechnology products through either a permit or notification procedures.

The decision to authorize the test is based on whether the item will pose a risk to the environment or agriculture. After several years of field testing, a petition may be submitted to USDA APHIS to deregulate the crop and allow commercialization of the product (Fernandez-Cornejo and Caswell 2006).

To date, APHIS has authorized over 13,000 environmental releases. From 1987 to April 2005, APHIS received over 11,600 applications and over 92 percent or approximately 10,672 have been approved (Fernandez-Cornejo and Caswell 2006). The peak year for approval was 2002, when 1,190 applications were approved. Over the same period, the majority of the applications approved for environmental release were for corn (5,000), followed by soybeans (2,560), potatoes (843), cotton (747), tomatoes (724), and wheat (552). In terms of GE traits, the majority of the applications approved were for varieties tested for herbicide tolerance (3,587), followed by insect resistance (3,141), improved product quality such as flavor, appearance or nutrition (2,314), virus resistance (1,239), agronomic properties such as drought resistance (1,843), and fungal resistance (647).

Because the regulations in 7 CFR 340 were first promulgated by APHIS in 1987, and were based on the authority of the Federal Plant Pest Act of 1957 (FPPA, Pub. L. 85-36) and the Plant Quarantine Act of 1912 (PQA), and there are additional statutory authorities in the PPA that were not in these Acts, it is desirable to consider revisions that would better align the regulations with the Plant Protection Act of 2000. APHIS has also gained biotech regulatory experience that should be incorporated into the regulations to improve the processes. Many technological advances have occurred, and these advances and potential future advances should be considered in developing the new regulations. In addition, APHIS is proposing changes to the regulations to reflect provisions of the 2008 Farm Bill recently enacted.

The Proposed Rule

The proposed amendments to 7 CFR 340 are based on issues addressed in the Draft Environment Impact Statement (DEIS) (July 13, 2007) and administrative changes necessary to align the regulations with the Plant Protection Act (PPA) of 2000 and provisions of the recently enacted 2008 Farm Bill. Details of the proposed changes can be found in the preamble of the regulations.

Benefits and Costs of the Proposed Rule

Benefits of the Proposed Rule

Benefits of the proposed rule include more efficient regulation of entities by APHIS under part 340; improved public understanding of and confidence in APHIS' biotech regulatory program; and improved clarity and transparency of the regulatory process. Several amendments of the proposed rule would improve the efficiency of APHIS' biotech regulatory process. These include the elimination of courtesy permits, the continued issuance of multi-year commercial permits, and the provisions of exemptions, performance-based shipping standards, and the inclusion of a provision that allows for exemptions to be established without having to amend the regulations.

Since the regulations were promulgated in 1987, there have been two major amendments; one took 5 months from proposed to final rule and the other took 20 months. Under the proposed regulations, exemptions could be provided without amending the regulations, resulting in considerable time savings. In addition there are several exemptions that are included in the proposed rule. Both the listing of exemptions and the provision to provide for exemptions without going through the rulemaking process would help reduce APHIS' rulemaking costs.

APHIS commits considerable resources to issuing courtesy permits for items that are not covered under part 340. The elimination of this process would improve efficiency and reduce the regulatory workload for APHIS. The Agency would not have to spend resources and the regulated entities would save time in not making unnecessary courtesy permit requests.

The Agency currently issues environmental release permits, including permits that are used for production of pharmaceutical and industrial compounds sold in commerce. In general, permits for releases of plants producing pharmaceutical or industrial compounds have been limited to a one-year duration. However, the proposed regulations provide a more useful and efficient approach to setting appropriate risk-related conditions in multi-year environmental release permits. Under the proposed system, APHIS would likely increase issuance of multi-year environmental release permits, thereby reducing the time the regulated entities need to spend submitting applications as well as the time APHIS spends reviewing the permit applications.

The proposal includes provisions to minimize unnecessary recordkeeping and reporting and to fine-tune this burden through particularized permit conditions to require only what is needed to ensure regulatory compliance based on individual cases. This should contribute to greater efficiency.

APHIS' biotech operations would be more streamlined under the proposed rule, in terms of required data submissions and administrative procedures. Lengthy descriptions of required applicant information would be replaced with more general information categories. These changes, along with more clearly defined categories for the environmental release permits, would potentially reduce the time entities, large or small, spend on the application process.

The proposed rule's greater clarity and transparency in comparison to the existing regulations is expected to enhance the general public's perception of APHIS' regulation of the

importation, interstate movement, and release into the environment of GE organisms. In particular, public-sector biotech research that is generally conducted on a much smaller scale than that of large agri-business enterprises can be expected to benefit from the proposed procedural changes to part 340.

In addition to the information provided in the regulation itself, guidance documents would be provided by USDA APHIS to assist in the preparation and submission of applications. Exemptions included in the proposed rule would yield time savings because the permit application process in those instances would be eliminated. Overall, the reporting burden would be minimized and this would allow for greater efficiency in the regulatory process.

Costs of the Proposed Rule

There are several costs associated with the proposed rule. The regulated entities would incur costs of becoming familiar with the regulatory amendments, providing additional information during the permit application process, and additional recordkeeping provisions of the proposed rule. In addition, there may be costs incurred in making any changes necessitated by the new permit process. Because in some instances the provisions of the proposed regulations are simply revisions of the current regulations, it is not expected that familiarization costs would be substantial. However, APHIS invites public comment on the costs the regulated community may incur with respect to rule familiarization and changes to their application systems. Various exemptions, performance-based shipping standards, and a streamlined permit process for the environmental release permits would provide cost savings to the regulated community.

USDA APHIS would incur costs in developing the guidance documents and providing outreach activities to inform the regulated community of provisions of the proposed rule. Training costs are expected to be incurred to familiarize the staff with the new permit system and

provisions of the regulations. As another area of cost to APHIS, the proposed rule would require that changes be made to the current system of permits.

The sections below outline the costs faced by regulated entities and the Federal government of current regulations and changes in costs that may occur with the proposed rule.

Regulated Community Costs

Regulated entities would incur costs through various recordkeeping, reporting and informational requirements of the proposed rule. Specifically, there are costs associated with rule familiarization. Entities in the regulated community that are unfamiliar with the regulations would have no transition costs. Another potential cost is the information that would have to be provided during the application process. The costs of collecting or developing this additional information and recording it in an application and records would vary, depending on current practices on the regulated entities. However, on average it is estimated that it would take an average of 2 hours to record this information in the permit application. Annual costs resulting from the additional recordkeeping may be estimated as the salary and associated costs for 640 additional hours of recordkeeping divided among 160 respondents. APHIS anticipates that any incremental costs to the regulated entities associated with record keeping and provision of information related to the proposed rule would not be large. In addition, the regulated entities may incur additional costs in updating their systems to allow for compatibility with APHIS' revised system of permits. Estimates of these costs are not available and therefore, APHIS invites public comments of the potential costs that affected entities may incur.

Government Costs

This section considers costs to USDA APHIS associated with the proposed rule. At present, costs to the Agency are incurred in the regulatory assessment and review of submitted materials. Under the current regulations, USDA APHIS activities include reviewing requests for and issuing permits and notifications, reviewing petitions, and developing environmental impact statements, and conducting environmental assessments. The proposal would change some of the information submitted and evaluated in the permit application process, but the activities associated with the process would remain largely similar to the current process, and it is not expected that permit process changes would increase the costs to USDA APHIS. The proposals to establish additional exemptions that could take the place of some permits and to discontinue courtesy permits, which have generally been issued at the rate of several hundred per year, would reduce permitting costs to a degree proportionate to the number of permits that no longer need to be issued.

USDA APHIS would potentially incur incremental costs conducting outreach activities for the proposed rule, developing guidance documents to ensure that the regulated community is familiar with the requirements of the rule, responding to information requests and providing staff training that may be necessary. In addition, in changing the permit system to accommodate requirements of the proposed rule, APHIS may potentially incur a one-time additional cost of $500,000. However the current system is adaptable to the new regulations and it is not anticipated that there would be any efficiency loss during the transitional period.

Initial Regulatory Flexibility Analysis

In accordance with the Regulatory Flexibility Act of 1980 (Public Law 96-354), this analysis considers the economic impact of the proposed rule on small businesses, small

organizations, and small governmental jurisdictions. Section 603 of the Act requires that the initial regulatory flexibility analysis (IRFA) be made available for public comments. This section addresses the IRFA requirements, as stated in Sections 603 (b) and 603(c) of the Act.

Reasons Action is being Considered

APHIS is taking action to amend 7 CFR 340, which regulates the interstate movement, importation, and environmental release of GE organisms that may be plant pests or that there is reason to believe are plant pests. The regulations in 7 CFR part 340 were promulgated in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912. These acts were subsequently subsumed within the Plant Protection Act (PPA) of 2000. The proposed revisions would be the first undertaken since enactment of the PPA and would bring part 340 in alignment with this Act. Advances in biotechnology and oversight experience gained by USDA APHIS have made it necessary to revise and update the regulations. The proposed changes would improve the regulatory process by providing greater transparency, flexibility, and efficiency.

Objective and Legal Basis for the Rule

The objective of this rule is to amend 7 CFR 340 to provide consistency with the 2000 PPA. In addition, the experience gained over the years would be incorporated into the proposed rule, yielding a more efficient process while controlling potential risk to plant health and the environment. This action is authorized by the Plant Protection Act of June 2000, as amended. The Plant Protection Act authorizes the Secretary of Agriculture to implement programs and policies designed to prevent the introduction and spread of plant pests and diseases.

Specifically, the Secretary of Agriculture is given the authority under the PPA to prevent the importation and interstate dissemination of plant pest and noxious weeds.

Description and Estimate of the Number of Small Entities Regulated

The proposed rule may affect a wide range of public and private biotech research facilities, biotech crop production, biotech seed production, food processors, grain processors, and paper producers that fall into various categories of the North American Industry Classification System (NAICS). For the purpose of this analysis and following the Small Business Administration (SBA) guidelines, the potentially affected entities are classified within the following sectors: Agriculture, Forestry, Fishing and Hunting (Sector 11), Manufacturing (Sectors 31-33), Wholesale Trade (Sector 42), Retail Trade (Sector 44 and 45), Transportation (Sectors 48 and 49), and Professional, Scientific and Technical Services (Sector 54).

For the Agriculture, Forestry, Fishing and Hunting sector, the subsectors of Crop Production, Animal Production, Forestry and Logging, and Support Activities for Agriculture and Forestry are potentially affected by this rule. The proposed rule may affect a wide range of establishments in the Crop Production category. Establishments in this category are considered small by SBA standards if annual sales are not more than $0.75 million. According to the 2002 Census of Agriculture, 97 percent of the farming businesses are considered small. Potentially affected crop-producing industries, with their NAICS codes in parentheses, are as follows: Soybean Farming (111110); Oilseed Farming (except soybean) (111120); Dry Pea and Bean Farming (111130); Wheat Farming (111140); Corn Farming (111150); Rice Farming (111160); Oilseed and Grain Combination Farming (111191); All Other Grain Farming (111199); Potato Farming (111211); Other Vegetable (except potato) and Melon Farming (111219); Orange Groves (111310); Citrus (except orange) Groves (111320); Apple Orchards (111331); Grape

Vineyards (111332); Strawberry Farming (111333); Berry (except Strawberry) Farming (111334); Tree Nut Farming (111335); Fruit and Tree Nut Combination Farming (111336); Other Noncitrus Fruit Farming (111337); Mushroom Production (111411); Other Food Crops Grown Under Cover (111419); Nursery and Tree Production (111421); Floriculture Production (111422); Tobacco Farming (111910); Cotton Farming (111920); Sugarcane Farming (111930); Hay Farming (111940); Sugar Beet Farming (111950); Peanut Farming (111960); and All other Miscellaneous Crop Farming (111970).

Some aspects of animal production may be affected because some GE plants are used for animal feeds and may have enhanced nutritional value or other benefits. In terms of animal production, potentially affected entities include ones within the following industries: Beef Cattle Ranching and Farming (NAICS 112111); Cattle Feedlots (NAICS 112112); Hog and Pig Farming (NAICS 112210); Sheep Farming (NAICS 112410); Goat Farming (NAICS 112420); and Apiculture (NAICS 112910). Except for Cattle Feedlots, entities in all of these industries are considered small by SBA standards if annual sales are not more than $0.75 million. Cattle Feedlot establishments are considered small by SBA standards if annual sales are not more than $2 million. According to the 2002 Census of Agriculture, 93 percent of Cattle Feedlot businesses, 99 percent of Beef Cattle Ranching and Farming businesses, 81 percent of Hog and Pig Farming businesses, 99 percent of Sheep and Goat farming businesses, and 99 percent of Apiculture businesses are considered small.

For the Forestry and Logging subsector the potentially affected establishments are classified within Timber Tract Operations (NAICS 113110); Forest Nursery and Gathering of Forest Products (NAICS 113210); and Logging (NAICS 113310). Establishments in the category of Timber Tract Operations and Forest Nursery and Gathering of Forest Products are considered small by SBA standards if annual sales are not more than $6.5 million and

establishments in the category of Logging are considered small if employment is not more than 500. According to the 2002 Survey of Business Owners, 99 percent of establishments in the Logging category are considered small. Neither the Census of Agriculture nor the Economic Census tracks revenue for establishments classified within Timber Tract Operations and Forest Nursery and Gathering of Forest Products.

In terms of Support Activities for Agriculture and Forestry, the potentially affected establishments are classified within Cotton Ginning (NAICS 11511); Soil Preparation, Planting, and Cultivating (NAICS 115112); Crop Harvesting (NAICS 115113); Postharvest Crop Activities (NAICS 115114); Farm Management Services (115116) Support Activities for Animal Production (NAICS 115210); and Support Activities for Forestry (NAICS 115310). Establishments in these categories are considered small by SBA standards if annual sales are not more than $6.5 million. However, neither the Census of Agriculture nor the Economic Census reports revenue for these establishments.

Entities that may be directly affected by the proposed rule in the Manufacturing Sector are classified within Ethyl Alcohol Manufacturing (NAICS 325193); Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325320); Pharmaceutical Preparation Manufacturing (NAICS 325412); and Medicinal and Botanical Manufacturing (NAICS 325411). Establishments in the Ethyl Alcohol Manufacturing category are considered small if they employ not more than 1,000 persons and those in the category of Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325320) are considered small if they employ not more than 500 persons. For both the Pharmaceutical Preparation Manufacturing (NAICS 325412); and Medicinal and Botanical Manufacturing (NAICS 325411) categories, establishments are considered small if they employ not more than 750 persons. According to the 2002 Economic Census, 98 percent of the establishments in the Chemical Manufacturing Sector had fewer than

500 employees and 99 percent had fewer than 1000. Therefore, businesses in the chemical manufacturing are predominantly small by SBA standards.

In terms of Wholesale Trade, entities that would be potentially affected may be found in the following categories: Fresh Fruit and Vegetable Merchant Wholesalers (NAICS 424480); Other Grocery and Related Products Merchant Wholesalers (NAICS 424490); Grain and Field Bean Merchant Wholesalers (NAICS 424510); Other Farm Product Raw Material Merchant Wholesalers (NAICS 424590); Farm Supplies and Merchant Wholesalers (NAICS 424910); and Flower, Nursery Stock, and Florists' Supplies Merchant Wholesalers (NAICS 424930). Establishments in the above categories are considered small by SBA standards if they employ not more than 100 persons. According to the 2002 Survey of Business Owners, 97 percent of the establishments in this category employed fewer than 100 people and are considered small by SBA standards.

Retail Trade, establishments that would be affected by the rules are in the following categories: Nursery and Garden Centers (NAICS 444220); Supermarkets and Other Grocery Stores (NAICS 445110); Fruit and Vegetable Markets (NAICS 445230); All Other Specialty Food Stores (NAICS 445299); Food (Health) Supplement Stores (NAICS 446191); Warehouse Clubs and Superstores (NAICS 452910); and Florist (NAICS 453110). Establishments in the Nursery and Garden Center, Fruit and Vegetable Markets, All other Specialty Food Stores, Food (Health) Supplement Stores; and Florist categories are considered small by SBA standards if annual sales are not more than $6.5 million. Supermarkets and Other Grocery Stores are considered small by SBA standards if annual sales are not more than $25 million. While the Economic Census reports total annual sales, the Census does not provide a breakdown of these establishments by revenue categories.

In terms of the Transportation sector, the potentially affected entities are in the category Farm Product Warehousing and Storage (NAICS 493130). Establishments in this category are considered small by SBA standards if annual sales are not more than $23.5 million. However, the Economic Census reports only total revenue for all establishments in this category.

In terms of Professional, Scientific and Technical Services, establishments in the category of Research and Development in the Physical, Engineering, and Life Sciences (NAICS 54170) may be affected. Establishments in this category are considered small by SBA standards if they employ not more than 500 persons. According to 2002 Economic Census, 82 percent of the establishments in this category are considered small.

Although data were not available on the business sizes for all potentially affected establishments, based on the foregoing information we can assume that the majority of the entities that may be affected by the proposed rule are small by SBA standards.

Given the aforementioned, a review of entities that have made application requests to APHIS shows that of the 420 applicants for the last 6 years, 263 were universities and colleges and public and private research institutions. The remainder of the applicants fall under various NAICS classification codes specified above but given time constraints their business size could not be readily determined. We were able to ascertain that the 263 institutions (63 percent) are large by SBA standards as they fall under NAICS code 54170 Research and Development in Physical Science. Establishments in this category are considered small by SBA standards if they employ not more than 500 persons. Even though the 2002 Economic Census suggests that 82 percent of the establishments in this category are considered small, the majority of applicants to APHIS are large by SBA standards.[3]

[3] The size determination was made using public information about these entities. This information was primarily obtained for the entities' websites.

Description and Estimate of Compliance Requirement

The proposed rule would require additional and modified information collections through recordkeeping, reporting, and notifications to APHIS when certain events occur. The proposed application process requires certain new information. The current and proposed rules both require submission of reports following an environmental release or field test, but the proposed requirement is more specific about the contents of such reports. Both the current and proposed rules require APHIS to be notified if an unauthorized release occurs or if during release the GE organism is found to have characteristics substantially different from those anticipated by the permit. The proposed rule is more specific about the types of records that must be kept for importations, interstate movements, and environmental releases, where the current regulations left more of these details to be specified only in permit conditions. In terms of record retention requirements, the proposed rule spells out a 2-year retention for records indicating that a GE organism imported or moved interstate reached its intended destination, and a 5-year retention for all other required records. By providing more specific information on what records are required, the proposed rule should alleviate some current burden that may result from persons keeping unnecessary records. In addition, APHIS has established the Biotechnology Quality Management System (BQMS), which is a voluntary compliance assistance unit within USDA APHIS. BQMS would facilitate the regulatory efforts of USDA APHIS by conducting outreach activities and providing compliance assistance to the regulated community. This would lessen any burden of the proposed rule to the regulated community.

Duplication, Overlap, and Conflict with Existing Rules and Regulations

APHIS has identified areas where the proposed rule will need to be closely coordinated with other Federal rules and statutory authorities. Coordination has been an important aspect of the daily implementation of the current regulation, and APHIS foresees additional areas for coordination under the proposed rule. In particular, APHIS will coordinate with the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). FDA regulates GE organisms under the authority of the Federal Food, Drug and Cosmetic Act and the Public Health Service Act (42 U.S.C. 262 et seq.), as appropriate. The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). As examples of areas that need coordination, some of the plant-incorporated protectants regulated by EPA are also subject to APHIS requirements under the PPA. Also, FDA is the primary U.S. agency responsible for ensuring the safety of commercial food and food additives, and FDA authority extends to any nonpesticidal substance that may be introduced into a new GE plant and that is expected to become a component of food. The proposed regulations would clarify the regulatory scope and procedures used by APHIS relative to these other agencies and improve the coordination process.

Significant Alternatives to the Rule

APHIS considered several significant alternatives during development of this proposed rule. We have compared the selected alternatives to others that were not selected to evaluate their feasibility and to consider whether any alternatives provide ways to minimize significant economic impacts on small entities. We have not identified any selected alternative that imposes disproportionate costs on small businesses, or any non-selected alternative that would both achieve the regulatory purposes and reduce costs for small businesses.

The selected alternative regarding the scope of the regulatory oversight was to add considerations of noxious weed risk in addition to evaluating plant pest risks, and to use genetic transformation, coupled with a determination by the Administrator as to whether a GE organism met certain risk-based criteria, as the trigger for regulation. Other alternatives considered included continuing to base the scope of regulation only on plant pest risks, or trying to develop a set of solely trait-based criteria that could be used to predict what articles would be regulated without the need for determinations by the Administrator. The first of these alternatives could have resulted in costs from damages caused by a GE plant with noxious weed aspects that was not regulated under the plant pest risks standard. The second alternative was not considered technically feasible, and could also have resulted in costs for persons who erroneously decide their GE plant is not within the scope of the regulations, but are overruled by a later determination by the Administrator that the GE plant is regulated.

The selected alternative for providing transparency and predictability to the permitting system was to establish permit categories for environmental releases of plants based on newly devised criteria. We also considered evaluating all requests for environmental release permits on a case-by-case basis, without categories. This alternative would have resulted in less predictability for applicants, and likely would have increased their costs for information collection because applications known to be in a particular category can contain less information about non-relevant areas.

The selected alternative regarding the duration period for permits was to make multi-year permits for interstate movement and importation more feasible by removing the one-year limit for interstate movement permits and the requirement to obtain a new importation permit for each imported shipment. We also considered alternatives to maintain either the current or alternative specific time limits for such permits. These alternatives would have resulted in additional costs

for applicants who would have to reapply for permits, rather than having the original permit issued with an appropriate duration.

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